

DEC - 1 2004

K033732 page 1/2

Safety & Effectiveness: MedTrade Products Antiseptic Barrier Silver Foam Dressing

Classification Name: 79 MGP, 878.4020 Dressing, Wound and Burn, Occlusive

Contact: Jonathan Ranfield - Director, Quality Assurance & Regulatory Affairs

Prepared: October 21, 2003

Description: MedTrade *Product's* Antiseptic Barrier Silver Foam Dressing is an exudate handling system intended for low to moderate exuding wounds. The antibacterial activity acting in the dressing is supported by laboratory testing demonstrating significant antibacterial activity against *Pseudomonas aeruginosa*, *Staphylococcus aureus* & *Escherichia coli*. The island dressing maintains a moist wound environment, which is conducive to optimal wound healing. During use the absorbent island gently expands as it takes up exudate. During use the lesion size may initially increase. This is normal and to be expected prior to wound granulation.

MedTrade *Product's* Antiseptic Barrier Silver Foam Dressing should be used under health care professional direction for the following indications: Pressure ulcers, Lower extremity ulcers, Venous, Arterial, Mixed etiology, Diabetic ulcers, Donor sites.

Dressings are supplied sterile in single use pouches. Product is gamma irradiated in accordance with the Sterilisation of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilisation, 3<sup>rd</sup> Edition (ANS/AAMI/ISO11137 – 1995) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991) for qualification for Method 1 for dosimetric release with a sterility assurance level of  $10^{-6}$ .

Packaging will consist of a single dressing in either a paper / paper or paper / poly pouch, the pouches will then be placed in to a sales carton, with an Instructions For Use Leaflet.

Biocompatibility testing including: Dermal Irritation, Dermal Sensitization, Cytotoxicity, Acute Systemic Toxicity and Hemocompatibility/Hemolysis have been successfully completed per ISO/Tripartite guidelines.

The MedTrade *Product's* Antiseptic Barrier Silver Foam Dressings are similar in design, composition and function to MedTrade Products Self Adhesive Foam Island Dressings 510(k) #K993627. A table of comparative features may be found below.

## COMPARATIVE FEATURES

Characteristics	MedTrade Product's Self Adhesive Foam Island Dressing	MedTrade Products Antiseptic Barrier Silver Foam Dressings
Composition	Hydropolymer Foam Island Dressing with medical pressure-sensitive adhesive coated on one side.	Hydropolymer Foam Island Dressing with medical pressure-sensitive adhesive coated on one side.
Backing Foam	Thickness 0.4mm± 10% Density 350-450 kgs/m <sup>3</sup> Tensile Strength >1 kg./25mm width at 0.4mm Elongation >200% at break	Thickness 0.4mm± 10% Density 350-450 kgs/m <sup>3</sup> Tensile Strength >1 kg./25mm width at 0.4mm Elongation >200% at break
Foam Island	Thickness 3+1mm	Thickness 3+1mm
Adhesive Coverage	100%	100%
Colour	Light Skin Tone	Light Skin Tone
Indications For Use	MedTrade Product's Foam Dressings should be used under health care professional direction for the following indications: Pressure ulcers Lower extremity ulcers, including: 1. Venous 2. Arterial 3. Mixed etiology Diabetic ulcers Donor sites	MedTrade Product's Antiseptic Barrier Silver Foam Dressings should be used under health care professional direction for the following indications: Pressure ulcers Lower extremity ulcers, including: 1. Venous 2. Arterial 3. Mixed etiology Diabetic ulcers Donor sites
Packaging	Printed Pouch	Printed Pouch
Sterilisation Method	Gamma Irradiation	Gamma Irradiation

Additionally, as with Maersk Medical's Arglaes-AB Antiseptic Barrier Dressing K99080 (attached), MedTrade Products Antiseptic Barrier Silver Foam Dressing has been shown to be an antibacterial barrier.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC - 1 2004

Mr. Jonathan Ranfield  
Director, Quality Assurance &  
Regulatory Affairs  
MedTrade Products Ltd  
Electra House  
Crewe Business Park, Crewe  
CW16GL United Kingdom

Re: K033732  
Trade/Device Name: Antiseptic Barrier Silver Foam Dressings  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: November 1, 2004  
Received: November 4, 2004

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Jonathan Ranfield

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for Miriam C. Provost*

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K033732

## Indications for Use

510(k) Number (if known): K033732

Device Name: MedTrade *Product's* Antiseptic Barrier Silver Foam Dressings

Indications For Use:

MedTrade *Product's* Antiseptic Barrier Silver Foam Dressings should be used under health care professional direction for the following indications:

Pressure ulcers

Lower extremity ulcers, including:

1. Venous
2. Arterial
3. Mixed etiology

Diabetic ulcers

Donor sites

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of \_\_\_\_\_

**510(k) Number** K033732